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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,371	12/10/2001	Ian R. Reid	HO-P02194US0	6234

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,371	REID, IAN R.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *0612/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8,9,11-15 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-4, 6, 8-9, 11-15, 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's response filed on 06/12/2006, wherein no amendment is filed.

Currently, claims 1-4, 6, 8-9, 11-15, and 22 are pending in this application.

Applicant's arguments have been considered, but not found persuasive, the rejection of claims 1-4, and 6 under 35 U.S.C. 102(b) as anticipated by Pak et al. (US 4,851,221 of record) and as evidenced by Merck Manual of Diagnosis and Therapy (17th ED) (1999) (PTO-892), and Bell et al. (Arch Intern Med 1992: 152: pages 2441-2444, PTO-892) in MAINTAINED. See under response to arguments.

Applicant's arguments have been considered, but not found persuasive, the rejection of claims 8, 9, 11-15, and 22 under 35 U.S.C. 103(a) as being unpatentable over Pak et al. (US 4,851,221 of record) in view of the Merck Manual of Diagnosis and Therapy (17th ED) (1999) (PTO-892), and further in view of Bell et al. (Arch Intern Med 1992: 152: pages 2441-2444, PTO-892) is MAINTAINED. See under response to arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, and 6 are rejected under 35 U.S.C. 102(b) as anticipated by Pak et al. (US 4,851,221 of record) and as evidenced by Merck Manual of Diagnosis and Therapy (17th ED) (1999) (PTO-892), and Bell et al. (Arch Intern Med 1992: 152: pages 2441-2444, PTO-892), rejection of record.

Pak et al. discloses that administering a calcium supplemental composition comprising calcium citrate at a dose 1g (60 meq/day) or 1.5-2.75 g calcium/day to a postmenopausal woman is useful in treating various conditions associated to a postmenopausal woman such as hypoparathyroidism, osteoporosis, bone loss, hyperphosphatemia and hypertension (see col.1 lines 49-50, 63-68; col.3 lines 42-43, 46; col.8 line 35-36; col.9 line 50-67; claim 20). Pak et al. disclose a daily administration. The calcium citrate composition of Pak et al. is prepared from pre-mix preparation with a calcium/citrate molar ratio of 1.25 of citric acid and a calcium compound such as calcium hydroxide (see abstract, and claim 18-20).

Furthermore, it is noted that, as evidenced by Bell et al. administration of calcium supplement, calcium carbonate (9.98 mmol [400 mg] of elemental calcium 3 times a day) to women between the ages of 55 + 9.3 yrs for 6 weeks i.e overlapping patient population as instantly claimed, resulted in 4.1 % increase in the high-density lipoprotein, and a 4.4 % reduction in the low-density lipoprotein cholesterol level. See abstract; page 2443, see under RESULTS.

Pak et al. does not expressly disclose the employment of the calcium composition in methods of increasing a high-density lipoprotein level (HDL) in plasma or the ratio of HDL to LDL in a postmenopausal women. Pak et al. does not expressly

teach that if the high-density lipoprotein level is increased, the administration is continued for at least about two months.

However, as discussed above, the host, a postmenopausal woman, and the amount of calcium citrate, in Pak reference are same as instantly claimed. Moreover, it is well known that cardiovascular diseases becomes more prevalent after menopause according to the Merck Manual of Diagnosis and Therapy. It is also well-known that the various conditions associated to a postmenopausal woman also include hypercholesterol levels due to menopause in need of increasing a high-density lipoprotein level (HDL) in plasma or lowering low-density lipoprotein level (LDL), or increasing a ratio of HDL to LDL in said postmenopausal woman.

Hence, according to Merck Manual, and as evidenced by Bell et al., the patient population in Pak et al. is deemed to encompass or overlap or even as same patient herein in need of increasing HDL level in plasma. Accordingly, the administration of the same compound to overlapping patient population, in the same effective amounts or doses of calcium citrate will cause the same effect, whether or not that effect is disclosed by the prior art.

Thus, with respect to the recitations wherein "high-density lipoprotein level in plasma is increased at least about 5 %", "high-density lipoprotein level in plasma is increased at least about 7.7 %", as in claims 2, 3, it is pointed out that from Pak's method, and as evidenced by Bell et al. administration of calcium supplements would inherently increase a high-density lipoprotein level (HDL) in plasma or a ratio of HDL to LDL in a postmenopausal woman. The increase of HDL would have been inherent by

administration of calcium citrate in 1 g dose per day. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Note that even the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable, or would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Response to Arguments

Applicant's argues that "There is no basis outside of speculation base on probabilities, that Pak population covers those of the instant claims or that the method of Pak would treat the condition addressed in the instant claims. A teaching of the use of calcium supplementation for treatment of osteoporosis says nothing about the usefulness, or lack thereof, of using calcium supplementation for treatment of hypercholesterol levels or unhealthy HDL and LDL levels." These arguments have been considered, but not found persuasive because Pak et al. discloses administration of calcium supplemental composition comprising calcium citrate at a dose 1g (60 meq/day) or 1.5-2.75 g calcium/day i.e the same effective amount as instantly claimed, to a postmenopausal woman for treating various conditions associated to a postmenopausal woman. As evidenced by Bell et al. administration of calcium supplement, 400 mg of elemental calcium 3 times a day to women between the ages of 55 + 9.3 yrs for 6 weeks

i.e overlapping patient population as disclosed by Pak, and as instantly claimed, resulted in 4.1 % increase in the high-density lipoprotein, and a 4.4 % reduction in the low-density lipoprotein cholesterol level. Accordingly, as disclosed by Pak, administration of calcium supplement to overlapping patient population, in the same effective amounts or doses of calcium citrate will cause the same effect i.e inherently increase high-density lipoprotein level in plasma, whether or not that effect is disclosed by the prior art.

Applicant's argument that "The examiner ignores the fact that what is not well known and what is not obvious, is that calcium supplementation is useful for postmenopausal women for treatment of unhealthy cholesterol, HDL and LDL levels" has been considered, but not found persuasive because contrary to Applicant's assertion, Bell et al. disclose that calcium supplements are useful in the treatment of hypercholesterolemia in women between the ages of 55 + 9.3 yrs i.e postmenopausal women.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 9, 11-15, and 22 are rejected under 103(a) as being unpatentable over Pak et al. (US 4,851,221 of record) in view of the Merck Manual of Diagnosis and Therapy (17th ED) (1999) (PTO-892), and further in view of Bell et al. (Arch Intern Med 1992: 152: pages 2441-2444, PTO-892), rejection of record.

Pak et al. is as discussed above.

Pak et al. does not expressly disclose measuring the high-density lipoprotein level in said woman.

Pak et al. does not expressly disclose the administration of calcium citrate for at least 6 months, for at least 12 months as in claims 8, 9, and 15.

Bell et al teaches that the administration of calcium supplement (9.98 mmol [400 mg] of elemental calcium 3 times a day) to women between the ages of 55 +9.3 yrs for 6 weeks, resulted in 4.1 % increase in the high-density lipoprotein, and a 4.4 % reduction in the low-density lipoprotein cholesterol level. See abstract; page 2443, see under RESULTS. It is further taught that calcium supplement was administered, and a complete lipid profile was measured at weeks 0, 6, and 12 weeks. See page 2442.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to measure the high-density lipoprotein level in postmenopausal woman who is administering calcium citrate for increasing HDL level.

One having ordinary skill in the art at the time the invention was made would have been motivated to measure the high-density lipoprotein level in a postmenopausal woman who is administering calcium citrate for increasing HDL level, since measuring

the lipoprotein levels including LDL and HDL in postmenopausal woman is a routine or standard practice in medical art as taught by Bell et al..

Furthermore, measuring cholesterols or lipoproteins levels of patients or humans before, during, and after therapeutic treatments, including with calcium, and determining the administration for at least for two or six months, are well known in the art and are considered well within conventional skills in medical practice and pharmaceutical science, involving merely routine skill in the art.

Response to Arguments

Applicant argues that "Pak and Bell are concerned with the treatment of distinctly different conditions, and there is no suggestion or motivation to combine the references, any combination of them does not teach the inventions of claims 8-9, 11-15, and 22". This argument has been considered, and not found persuasive as discussed above, and those found below.

Though Pak et al. does not expressly disclose measuring high-density lipoprotein level, and administration of calcium citrate for at least 6 months in postmenopausal women, for at least 12 months as in claims 8, 9, and 15, from the teachings of Bell et al., it would have been obvious to a person of ordinary skill in the art at the time the invention was made to measure cholesterols or lipoproteins levels of patients or humans before, during, and after therapeutic treatments, including with calcium, and to determine the administration for at least for two or six months. Further, measuring cholesterols or lipoproteins levels of patients or humans before, during, and after therapeutic treatments, including with calcium, and determining the administration

for at least for two or six months, are well known in the art and are considered well within conventional skills in medical practice and pharmaceutical science, involving merely routine skill in the art.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER